Navigated Pedicle Screw Placement in Lumbar Spine Fusion Surgery

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Introduction

For the treatment of spinal instabilities arising from injuries, tumors and deformities devices with the use of transpedicular screws has become a routine procedure since the introduction by Roy-Camille [25]. However, due to the small diameter and its relation to neural structures and the screws are directed to major vessels, these technique may lead to serious complications due to misplacement of these screws [6].

Most surgeons use fluoroscopy for localizing the pedicle. But with this conventional technique the cortical perforation rate is high. Within the lumbar spine the misplacement rate is up to 30 [9, 27]. Within the thoracic spine the pedicle placement is more difficult because of the smaller diameter of the pedicle and the closeness of the spinal cord. In the literature cortical perforations of the pedicle are described up to 55 percent [29]. The incidence of neurological complications arising of such misplacements is described up to 5% [6, 9, 18]. In some cases even a placement through the cauda equina is described [5].

But also from the biomechanical point of view it is useful to hit the pedicle as precise as possible. The better the screw fills the pedicle, the higher is the fixation strength [2]. This effect is higher with a screw as long as possible.

CT-Based Navigation

To decrease the misplacement rate computer assisted spinal navigation systems has been developed in the nineties as first application in orthopaedic surgery. In the beginning these systems were CT based. The advantage of these technique is the three dimensional visualization of the pedicle in axial, sagittal and coronal planes allowing the observation of the placement in relationship to the anatomy structures and the possibility of a pre-operative planning of the pedicle screw. The disadvantages are the image acquisition pre-operatively with the possibility of motion of the vertebra during the interim between the scan and the operation itself [4]. Furthermore, there is the need of the so-called registration meaning the correlation of the patient's anatomy and the data on the computer.

The registration, also called »matching« is the most important step in CT-based navigation. There are two different kinds of procedures.

- *Pair-point-registration:* At least three, due to own experience up to five points, not on a straight line, are identified on the surface as well as on the therapeutical as on the virtual object. Preoperatively these points are marked on the virtual object at the navigation system. These points should have an as large distance as possible and should be on different levels. Intraoperatively the corresponding points are localized on the therapeutical object. These points are digitalized with an instrument recognized by the navigation system, the so called »pointer«. Due to the pairs of the corresponding points the computer can calculate the position of both coordinate systems, the virtual and the real one, and overly both.
- *Surface registration:* Using this registration technique, a three dimensional model of the bony surface of the CT-dataset is calculated pre-operatively. Intra-opera-

tively a cloud of several points is digitalized on the real bony surface. The computer calculates these points to the surface of the model. These points should be as symmetric as possible on the posterior cortex of the vertebra, including the posterior process.

Most navigation systems use both registration forms to increase the accuracy. Each vertebra should be registrated on its own due to the flexibility of the spine. The CT-scan is performed on the back, operation in prone position. This can change the position and relationship between the segments, as well as intra-operative movements. The single vertebra itself is a rigid body. Therefore the registration for each vertebra can be performed independent from the positioning of the spine. The DRB has to be placed to each vertebra that is operated on at the posterior process.

Several authors [17, 26] reported a longer insertion time per screw, however the total operation time was not reported to be significantly longer [17, 28]. Despite to these limitations with the use of computer assisted spine surgery the misplacement rate could be decreased to 4.5 to 10% [1, 17, 19, 20, 28]. Furthermore, no neurological complications were described in the actual literature placing pedicle screws with computer assistance.

However, there are several pitfalls to avoid during CT based spinal navigation. While calculating the surface of the vertebra the surface might not be calculated correctly due to an osteoporotic bone or other artifacts like pointing with still soft tissue on the bone. With an incorrect surface calculation the position of the vertebra might be calculated incorrect leading to the mistake that the pedicle screw is displayed on the correct position on the monitor screen but is wrong in reality.

Fluoroscopy-Based Navigation

The limitations of the CT-based navigation is absent in fluoroscopy based navigation. Within this navigation technique the registration process is automated and there is the possibility of updating the dataset due to new acquisition of fluoroscopic images at any time during surgery. The limitation is the two dimensional image information and the decreased image quality within the thoracic spine.

A definite improvement of the navigation systems within the last past years is the implementation of intra-operative fluoroscopy and to use these images for the navigation (modality based navigation). These actual images can be used multimodal for navigation (spine, pelvis, extremities). The images can be actualized after reduction or an additional plane can be integrated. Furthermore the orthopedic surgeon is familiar with the intra-operative use of a fluoroscope.

The principle of fluoroscopy based navigation in the spine is: The DRB is placed to the posterior process in the known manner. With the fluoroscope an a. p. and a lateral view is taken. With small rotation of the fluoroscope out of the a.p. it is possible to perform oblique views of the vertebra as well. The images are placed into a »library« at the navigation system. If the image quality is good, the fluoroscope can be removed from the operation situs. The surgeon can choose the images to navigate in. There is a maximum of four views displayable simultaneously. Without a paired-point or surface registration it is possible to navigate the instruments within these images. The images will be stay static on the monitor and the instruments are displayed in real time. Beneath the advantages of multiplanar visualization in real time a reduction of the radiation exposure is possible.

The accuracy of Fluoroscopy spinal navigation is quite as precise as CT-based navigation

Choi [3] performed an experimental study using cadaver specimens from T1 to S1 comparing the accuracy of a CT-based navigation system vs. a fluoroscopy based robot system. In his study he found 12.7% perforations within the CT-navigated group vs. 17.9% misplacements in the fluoroscopy based group.

Fritsch used fluoroscopy based navigation for pedicle screw placement in 30 patients within a clinical evaluation. Within a postoperative CT-scan the evaluation of the placement was performed. 5.6% of the screws showed misplacement, divided in 9% in the thoracic spine and 3.8% in the lumbar spine.

In a recently published study Rampersaud [21] found an overall pedicle wall breach of 15.3% within a clinical study. The pedicle screw placement was performed between T2 and S1. Evaluating the misplacement in thoracic and lumbar spine the rate within thoracic spine was significantly higher with 31.6% vs. 10.6% in the lumbar spine. Due to an associated error of 1–2 mm due to metal artefacts [22, 30] he rated misplaced screws of below 2 mm as clinically acceptable resulting in a misplacement rate of 5.1% in the thoracic and 1.4% in lumbar spine.

Iso-C-3D-Based Navigation

The newly developed Iso-C-3D (Siemens, Erlangen, Germany) allows directly intra-operative three dimensional imaging in multiplanar views due to multiple fluoroscopic images around an isocenter [15, 24]. The scanned volume is 12 cm^3. The scan itself takes 120 seconds with a fluoroscopy radiation time of 20 seconds. This new intra-operative three dimensional method correlates accurate with imaging with computer tomography [7, 16, 23].

In alliance with a computer-assisted surgery system the combination of this three dimensional dataset with the advantages of the fluoroscopy based navigation is given. No anatomy based registration is necessary due to an automated registration process during the scan. Furthermore data update is possible at any time during surgery with a new scan.

There are only a few reports for Iso-C-based navigation for pedicle screw placement. Grützner [10] reported in a clinical study with 302 pedicle screws implanted with Iso-C-3D navigation of a misplacement rate of more than 2 mm in 1.7%. In an earlier paper of the same group Wendel [28] reported of 0.7% misplacements in 141 screws. In his paper he compared the misplacement rate with CT- and fluoroscopy based navigation within the same hospital. In the »historical« comparison group 4.5% of the CT based and 2.8% of the fluoroscopy based navigated pedicle screws were misplaced. The misplacements with Iso-C-based navigation occurred in the thoracic spine.

Hott evaluated the clinical screw placement in 86 placements from cervical to lumbar spine. He reported of 4% misplacements in cervical, 6% in thoracic and non in lumbar spine [12].

Holly [11] performed a laboratory evaluation of the Iso-C navigation using three fresh-frozen intact human torsos. For this study he placed a reference to a spinous process and performed the navigated screw placement at this level and one above and below. Pedicles of T1 down to L5 were instrumented. For image-guided drill placement a small skin incision was made therefore. Of 102 pedicle screws 94.7% were placed correctly, 100% in lumbar and 92% in thoracic spine.

Within the thoracic spine the misplacement rate was higher than in the lumbar spine. This overall misplacement rate is smaller compared with the pedicle perforation rate using CT or fluoroscopy based navigation. However, there is the question of the reason for this rate. Within the reported clinical cases no reason for this small inaccuracy was reported, neither a movement of the reference base or other reasons like the influence of freehand placement.

Pitfalls

One mistake during navigation with one of the above mentioned modalities is the right definition of the vertebra to operate on. The correct localization must be defined by the surgeon. Within the lumbar spine most time this is easy, but it is still necessary to use a fluoroscope to verify the correct high. Within the thoracic spine a fluoroscope is essential to localize the right posterior process of the navigated vertebra.

Precision Analysis of CT and ISO-C Navigation

The purpose of an own study was to evaluate the basic accuracy of the CT and Iso-C-based navigation due to the above-mentioned difference in precision. Therefore, an experimental study was performed using a plastic model of a whole spine with the help of the »reversed verification« described by Hüfner et al. [14].

Methods

The Surgigate™ navigation system (Medivision, Oberdorf, Switzerland), either the spine module, version 3.1 or the Iso-C module, version 1.0 was used.

An intact foam model of the entire spine (Synbone™, Malans, Switzerland) from C1 to sacrum was marked with titanium markers, 1.6 mm in diameter and 8 mm length at level Th4, Th8, Th12, L2, and L4. These markers were placed at the five vertebras at the lateral side of the pedicle, the lateral side of the vertebra, and ventral at the inferior and superior edge of the vertebra.

A CT scan of this spine in supine position was performed using the volume zoom scanner (Siemens, Erlangen, Germany) with the following protocol: 120 kV, 150 mAs, Thick slices 1.25 mm, table feed 5.5 mm, reconstruction interval 0.6 mm. The marked vertebra, one above and two below were scanned. The reason for scanning two vertebras below was the overlapping anatomy of the spinal process within the thoracic spine [8].

For CT-based navigation the matching was performed using five defined landmarks: tip of the spinous process and superior and inferior facet on both sides. This procedure was performed at each vertebra marked with the titanium marker. The reference base was placed to the spinous process and the registration was performed. Once the matching has been calculated, a number, witch reflects the quality of the registration is displayed. The matching result is the root-mean-square of the distances between the digitized points projected into the CT images and their corresponding points in the image. Using the Calculate/Skip worst button the system enables a new calculation with one pair less, the worst one. The new matching result is then displayed.

If this matching result is larger than 1 the pair point matching was repeated.

Surface matching was performed afterwards when the given result of the calculation was good. It was performed with 12 points symmetrically at the dorsal aspect of the vertebra including the spinal process. Again, if the matching result was larger than 1 the surface matching was repeated.

For Iso-C navigation the reference base was also placed rigidly to the marked vertebra. The isocenter was defined with an ap and a lateral fluoroscopic image placing the vertebra centrally. Therefore the whole spine was placed into special holders at both ends of the spinous model to verify that no other metal is in the x-ray beam. Both holders were placed upon a radiolucent table, also (◘ Fig. 71.1).

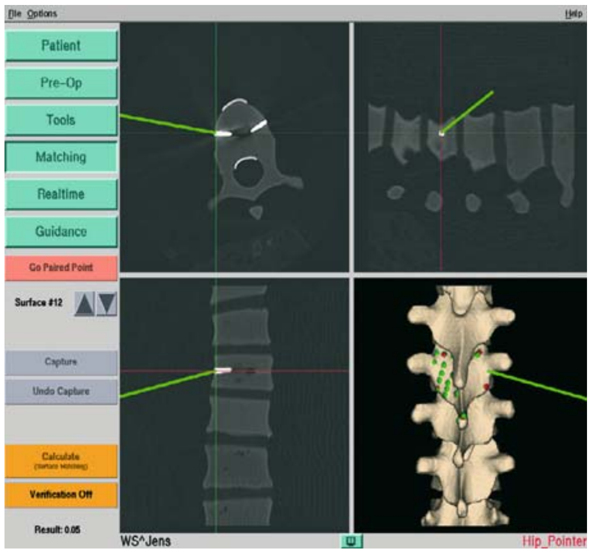
With two different setups the accuracy analysis was performed:

Point Accuracy

The accuracy at the placed markers were analyzed. Within the verification mode the pointer has to be placed to a selected point and this position should be compared with the displayed point within the dataset. According to Hüfner [14], we also used the »reversed verification«.

Therefore, the pointer was placed after the registration procedure in a special holder. This holder allows a three-dimensional movement of the pointer until the tip of the virtual displayed pointer hit a marker on the navigation system (◘ Fig. 71.2). Fixing the holder rigidly the distance in reality between the marker and the tip of the pointer was measured. An electronically calliper (CD-15CP, Mitutoyo, Inc., Aurora, IL) was used (◘ Fig. 71.3). The accuracy of the calliper was 0.1 mm, according to the manufacturer. All six titanium markers at each marked vertebra were selected as reference points for this reversed verification.

◘ **Fig. 71.1.** »Reversed Verification«: At the navigated vertebra the reference base is placed at the spinous process. In a special three-dimensional holding device the pointer is fixed allowing free movement of the pointer in space. The device can be fixed when achieved the correct position of the pointer



◘ **Fig. 71.2.** Monitor screenshot: The pointer was fixed with the holding device when hitting the titanium markers displayed on the monitor screen

Fig. 71.3. With an electronic calliper between the titanium marker and the tip of the pointer the deviation in reality was measured

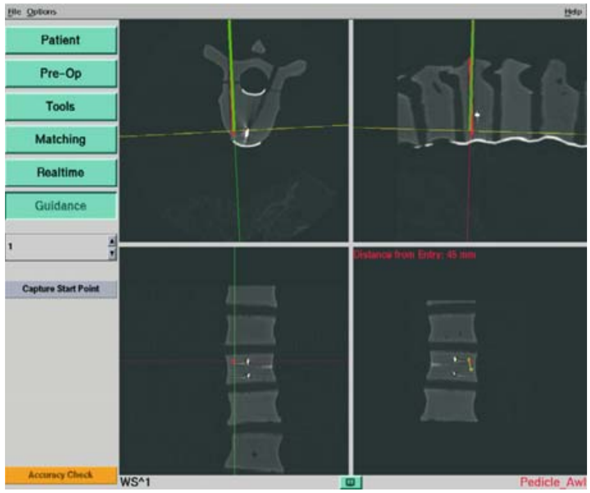


Fig. 71.4. Monitor screenshot: In the prepared holes a trajectory (*red*) was planned and the navigated pedicle awl was placed into the drill hole. The deviation of the angle and the deviation of the entrance point was measured on the screenshot

Pedicle Accuracy

The accuracy for pedicle screw placement was analyzed placing drill-holes for a pedicle screw at Th4, Th8, Th12, L2, and L4 with the navigated pedicle awl of the navigation system. The placement was performed manually without navigation. A CT scan with the same protocol mentioned above was performed of each instrumented vertebra with one vertebra above and two below.

A trajectory was exactly planned within the canal for the pedicle screw witch was visible within the dataset. The diameter of the trajectory was planned as 4 mm, the diameter of the pedicle awl.

For registration same landmarks as for pair-point-matching and surface registration as mentioned above was used. The reference base was placed at the prepared vertebra.

After registration the pedicle awl was placed to the prepared drill hole exactly fit the hole without any motion due to preparing with the same instrument. The navigated awl was displayed on the navigation monitor in green as a line. A screenshot of the monitor was performed and transferred to a commercial laptop. Using CorelDraw 7 (Corel Corperation, Otawa, ON), the screenshots were analyzed measuring the deviation of the planned trajectory and the displayed pedicle awl. The maximum difference between both lines and the angular deviation in each direction was measured (Fig. 71.4).

The analysis at each vertebra was performed three times at all markers or at the left and right pedicle with a new registration, either CT based or with a new Iso-C scan, in between.

Results

Point Accuracy

The mean deviation using CT-based navigation was 1 mm including all markers at one vertebra at the whole spine and 0.5 mm with Iso-C navigation. However, the difference was not significant.

The highest deviation with the CT-based navigation was 2.8 mm, with Iso-C-based navigation 1.88 mm. In almost fifty percent of the measurements a correct imaging, e.g. no difference in reality, was registered with Iso-C navigation. This was just in 25% with CT-based navigation the result. A deviation of more than 2 mm was not registered with Iso-C navigation, in 12% of the CT-based procedure (Fig. 71.5).

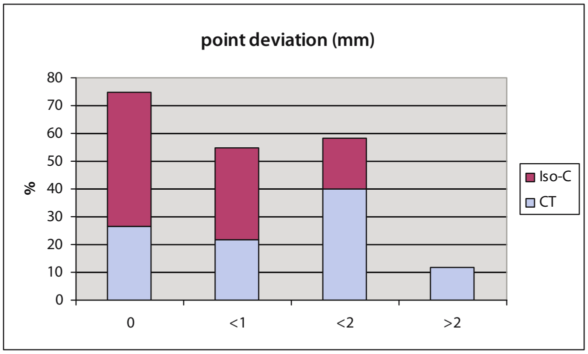


Fig. 71.5. Iso-C-based navigation showed a higher point accuracy. However, between both modalities there was no statistical difference

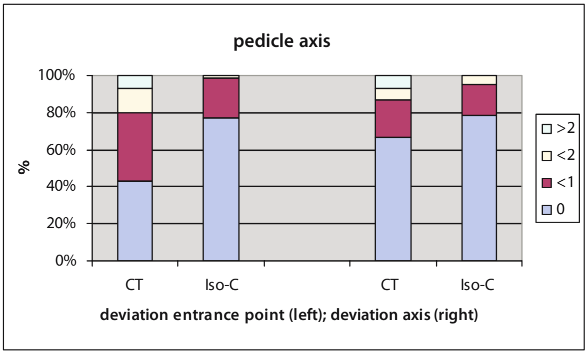


Fig. 71.6. *On the left side* the deviation at the entrance point of both navigation modalities is shown in mm. *On the right side* the deviation of the pedicle axis is shown. Between both navigation modules there is no statistical significance

Pedicle Accuracy

The mean deviation in CT-based navigation was 0.78 mm with a maximum deviation of 4 mm. Iso-C-3D-based navigation showed a maximum deviation of 1.5 mm with a mean deviation of 0.23 mm. Over 75% of the measurements showed no deviation at the entrance point with Iso-C-3D based navigation in contrast to 43% with CT based navigation. No deviation higher than 2 mm occurred with Iso-c-3D based but in 6.6% in CT based navigation (Fig. 71.6).

Almost 80% of the pedicle axis of the inserted pedicle awls hit the defined trajectories correct with Iso-C-3D navigation. In less than 5% an angle of 1 to 2 degree and no deviation greater than 2° occurred. In CT based navigation two third of the inserted pedicle awls showed no deviation. However, a deviation of more than 2° occurs in 6.6%.

The mean deviation in Iso-C-based navigation was 0.2 degree with a maximum deviation of 1.9°. CT-based navigation showed a mean deviation of 0.6 degree with a maximum of 4.5° (see Fig. 71.6).

Discussion and Conclusion

During CT-based navigation, pPossible errors and inaccurate point registration and therefore miscalculations of the dataset can be achieved. The planned landmarks have to be reproduced accurately for CT-based navigation. The time-consuming step of registration is automated in Iso-C-based navigation. This special point might be the reason for higher accuracy using Iso-C-based navigation for pedicle screw placement.

Within this experimental study, the accuracy compared to CT-based navigation was not significant different. However, comparing the measured accuracy in point as well as in pedicle accuracy the Iso-C-based navigation is more accurate. Furthermore with Iso-C-based navigation no special CT has to be prepared preoperative. an update of the dataset is always possible performing a new Iso-C scan if an anatomic change occurs intra-operatively.

The disadvantage of decreased image quality in osteopenic or obese patients as described by Hott [11, 13] has to be mentioned but was not present in the experimental setup, of course. However, this point has to be considered during Iso-C-based navigation especially in thoracic spine.

The overall accuracy of both three dimensional navigation tools is accurate. In the literature the misplacement rate for pedicle screw placement is slightly higher using CT-based navigation compared to Iso-C-based navigation. However, the amount of literature concerning CT-based spinal procedures is higher than of the most recent technological advantage in navigation using a combination with the Iso-C. The question to answer was if the recently published studies evaluating the Iso-C are concurrence good due to a small number of patients or if the Iso-C-based navigation provides a higher accuracy than CT based navigation.

With this experimental setup concerning the overall image to reality accuracy using a »reversed verification« model, we were able to proof a higher accuracy for Iso-C-based navigation. Within this technique combining a »fluoroscope« with three dimensional navigation it offers some advantages over CT- or Fluoroscopic based navigation. A true three-dimensional dataset with automated registration will broaden the application in spinal surgery providing a high accuracy. Furthermore the applications of minimal invasive techniques in spinal surgery seem possible.

Due to the performed study and resulting accuracy results we will still advice using intra-operative fluoroscopy for intra-operative control of the displayed accuracy of both modalities.

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